K110757
page 1 of 2

510(k) SUMMARY
(in accordance with 21 CFR 807.87(b) and 21 CFR 807.92)

TL-Cermide Skin Emulsion

AUG 19 2011

1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

RRI Group, Inc.
248 Latitude Lane, Suite 104
Lake Wylie, SC 29710

Phone: (803) 831-7657
Fax: (803) 831-1494

Contact Person: Lara Noah
lnoah@rriint.com

Date Prepared: July 20, 2011

2. Name of Device and Name/Address of Sponsor

TL-Cermide Skin Emulsion

Trigen Laboratories, Inc.
2400 Main Street Ext., Suite 6
Sayreville, NJ 08872

Common or Usual Name

Dressing, Wound & Burn, Hydrogel w/drug biologic

Classification Name

Device	Unclassified
Review Panel	General & Plastic Surgery
Product Code	FRO
Unclassified Reason	Pre-Amendment
Submission Type	510(k)

3. Substantial Equivalent Devices:

Trigen Laboratories Inc. believes that TL-Cermide Skin Emulsion is substantially equivalent to the currently marketed device, EPICERAM® Skin Barrier Emulsion (Radiodermatitis Emulsion) cleared under K052643.

4. Device Description:

   TL-Cermide Skin Emulsion is a steroid-free, fragrance-free, ceramide-dominant formulation

5. Intended Use Indications for Use:

   TL-Cermide Skin Emulsion is to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, and radiation dermatitis. TL-Cermide Skin Emulsion helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process

6. Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s):

   All products referenced are non-sterile emulsions that are applied topically to relieve the symptoms of various dermatoses, including, but not limited to atopic dermatitis, irritant contact dermatitis and radiation dermatitis.

7. Conclusions:

   Functional and performance testing has been conducted to assess the safety and efficacy of TL-Cermide Skin Emulsion and the results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

RRI Group, Inc.
% Ms. Lara Noah
Senior Manager, Regulatory Affairs
248 Latitude Lane, Suite 104
Lake Wylie, South Carolina 29710-1457

AUG 19 2011

Re: K110757
Trade/Device Name: TL-Cermide Skin Emulsion
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 20, 2011
Received: July 21, 2011

Dear Ms. Noah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

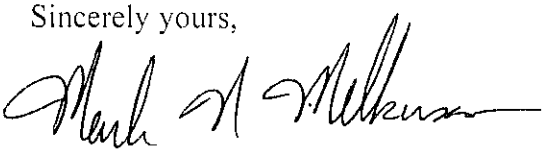
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110757

Device Name: TL-Cermide Skin Emulsion

Indications For Use:

TL-Cermide Skin Emulsion is to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, and radiation dermatitis. TL-Cermide Skin Emulsion helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for M&M
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110757